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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/517,812	12/14/2004	Harald Breivik	01526.400400	8613

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EXAMINER	
CARR, DEBORAH D	

ART UNIT	PAPER NUMBER
1621	

MAIL DATE	DELIVERY MODE
04/17/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/517,812	BREIVIK ET AL.	
	Examiner	Art Unit	
	DEBORAH D. CARR	1621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *21 December 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *32-35,38,39,42-50 and 59-61* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *32-35,38,39,42-50 and 59-61* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *21/2008, 2/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed 21 December 2007 have been fully considered but they are not persuasive. The rejection of claims 32-39, 42-50, 59-61 under 35 USC§112, 1st paragraph is maintained, as are the rejections of claims 32-35, 38-39, 42-50, 5961 under 35 USC§102(b).

2. Claims 36-37, 40-41, 51-58 have been canceled and claims 59-61.

3. Claims 32-35, 38, 39, 42-50 and 59-61 are pending.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 32-35, 38, 39, 42-50 and 59-61 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant argues the specification as originally filed is in compliance with the written description requirement since only requires that the specification disclose information

sufficient to show that the inventor possessed the invention at the time of the original disclosure.

Accordingly, one of ordinary skill in the art would have recognized that the inventors were in possession of a pharmaceutical composition comprising marine oil that comprised EPA ethyl ester and DHA ethyl ester in a pharmaceutically effective concentration to therapeutically treat hypertriglyceridaemia at the time of the original disclosure. Since treatment dosages are not claimed, they need not be disclosed to satisfy the written description requirement.

There was never a question of whether or not applicant was in procession of the pharmaceutical composition. However the written description for the "pharmaceutically effective concentration to therapeutically treat hypertriglyceridaemia" is not present. Applicant" statement that "treatment dosages are not claimed" is questionable since the EPA/DHA esters are administered in a "pharmaceutically effective concentration to therapeutically treat hypertriglyceridaemia" which is basically a dosage.

As to applicant's arguments regarding the amounts given for various pollutants such as PCDD, PCDF, & TE PCB not being disclosed in the specification, the argument has no merit. Applicants point towards section 2163.05 in the MPEP wherein *In re Wertheim* discusses ranges. It should be noted the range is actually the fact clearly show an actual range wherein another range was lifted out of.

The instant specification does not recite a specific range nor does Fig. 2 recite a specific range. Figure 2 shows that under specific process parameters pollutants were reduced to a specific concentration. This is no other data supplied to show that the stripping process used further reduces the pollutants in the fish oil. Also it should be noted that none of the pollutants removed and captured in Fig. 2 is BDF-47. Therefore applicants cannot point to Fig. 2 as a means of supplying a written description for BDF-47.

Also Fig. 2 does not supply a written description for increasing the amounts of both ethyl esters to pharmaceutically effective concentrations to therapeutically treat hypertriglyceridaemia.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 32-35, 38-39, 42-46, 60-61 rejected under 35 U.S.C. 102(b) as being clearly anticipated by EPAX Product Specifications for EPAX 4020EE or 5500EE or 6000EE or 6010EE.

Applicant arguments state the following:

> Applicants believe that the only EPAX products containing EPA ethyl ester and DHA ethyl ester that were sold in the United States before the July 1 1,2002, priority date of the present application were EPAX 5500EE and EPAX 6000EE. Accordingly, at

> least EPAX 4020EE and 6010EE and their product specifications are not prior art to the present application.

It should be noted that the word "or" to separate the requirements used in the 102(b) statement. While EPAX 4020EE and 6010EE may not have been on sale in the US prior to July 11, 2002, they were described in a printed publication in this or a foreign country more than one year prior to the date of the instant application for patent in the United States.

As to the references not teaching a "pharmaceutically effective concentration to therapeutically treat hypertriglyceridaemia" this argument also has no basis. EPAX 4020EE, 5500EE, 6000EE and 6010EE are supplements sold by EPAX AS after many years of testing and clinical research to treat various condition-specific conditions. In order to affectively treat said condions, the ethyl esters would have to be present in pharmaceutically effective concentrations.

All four EPAX products listed supra are marine oils containing both eicosapentaenioc acid ethyl ester and docosahexaenoic acid ethyl ester in a pharmaceutically effective concentration to therapeutically treat hypertriglyceridaemia (See the attached product sheets).

While the European Pharmacopoeia states that 80% is the minimum amount required to treat hypertriglyceridaemia, EPAX clearly shows that concentrations below 80% is effective. (See EPAV 5500 EE fact sheet).

8. Claims 47-50, 59 rejected under 35 U.S.C. 102(b) as being clearly anticipated by Dam et al.

Applicants have restated the arguments supra for this rejection. The response pertaining to the whether or not Omacor™ is applicable due to its date of sale in the US are applied here also. As to the pollutant levels in Omacor™, see the attach product fact sheet describing the process of obtaining Omacor™ for use.

Conclusion

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to DEBORAH D. CARR whose telephone number is (571)272-0637. The examiner can normally be reached on Monday-Friday 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on 571-272-0871. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Deborah D Carr/
Primary Examiner
Art Unit 1621

Ddc